

**REMARKS**

Claims 15-20, 23-32 and 42-44 remain pending in this application. Claims 1-14, 21, 22 and 33-40 have been cancelled, without prejudice. Claims 27, 29 and 42 are amended to correct errors in antecedent basis.

Claims 15-20, 23-32 and 42-44 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 15-17 and 21-26 of copending U.S. Application Serial No. 10/869407. Without commenting on the substance of the provisional rejection, Applicant submits that this application should be permitted to issue without the need of a terminal disclaimer as this application is the earlier-filed of the two applications and there is no other grounds of rejection. See MPEP §804.I.B.1.

Claims 15-20 and 30-32 stand rejected under 35 USC §102(b) as being anticipated by US Patent No. 5480424 (“Cox”). Applicant respectfully traverses the rejection.

The inventive valve defined in independent claim 15 requires a flexible sleeve having a proximal end, a distal end and *an outside surface*; at least one cusp configured to permit blood flow through the at least one cusp in a single direction; *at least one ring attached to the outside surface* at only the proximal end of the sleeve, the at least one ring being attached to a portion of the sleeve that is not everted; and at least one fastener extending in a direction radially outward with respect to the sleeve. Thus, among other elements, the valve includes a sleeve that has an outside surface and at least one ring that is attached to the outside surface.

Cox on the other hand describes a valve that has an annuloplasty ring attached to the inlet axial end of the valve, and is clearly not attached to the outside surface of the sleeve. The arrangement of the elements of Cox’s device are described at column 23, lines 8-12: “After obtaining a tubular segment of tissue or synthetic material, *the tubular segment is sutured at its inlet end to a round annuloplasty ring* which is then sutured into the aorta (or pulmonary

artery) at the level of the lowest point of the excised native semilunar valve.”<sup>1</sup> The annuloplasty ring of Cox is thus used to “help create a bridge between the *inlet end* of the tubular tissue segment, and a valve annulus in a patient (such as a patient whose native mitral valve annulus is weak, dilated, and/or "rounded" out of its normal shape).” Cox, col 20:55-59. If the inlet end of the valve and the native valve site are not a match--i.e., the native valve site is out of round or dilated--the annuloplasty ring, when sutured to the valve site is used as a “bridge” from the valve site to the artificial valve. The end result is that when the Cox device is implanted, blood flows to the valve site, passes over the annuloplasty ring and then into the artificial valve.

The ring of the current invention is attached to the outside surface of the sleeve. See Figure 11 (“The sleeve is secured on its inside surface to the valve and on the base of its outside surface to a compressible annulus, the mounting ring (85).” Stevens, US Publication No. 20020058995, paragraph 48.) In contrast, as discussed above, the annuloplasty ring of Cox acts to “bridge” differences in shape and diameter between the native valve site and the artificial valve because it is attached at the inlet axial end of the valve. As a result, Applicant submits that Cox fails to describe each element of the claimed invention, and seek withdrawal of the rejection.

Claims 23-26 stand rejected under 35 USC §103(a) as being unpatentable over Cox as applied to claim 15, and further in view of US Patent No. 5840081 (“Andersen”). Applicant respectfully traverses the rejection. As discussed above, Cox does not teach the element of a ring attached to the outside surface of the sleeve. Further, Andersen describes a stent structure that is attached to a valve at its commissural points, and therefore does not describe a valve having “at least one ring attached to the outside surface at *only the proximal end of the sleeve*. Thus, any combination of the references does not disclose each and every element of the claimed invention. Further, Applicant submits that substituting the “ring” of Andersen would not be obvious to one skilled in the art as it does not serve the purpose of bridging the valve to the valve situs as is discussed in Cox. Applicant requests that the rejection be withdrawn.

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<sup>1</sup> Annuloplasty rings are “foreign objects that come into direct contact with blood (and which typically have rough surfaces, to facilitate sewing) ....” Cox, col 20:31-35.

Claims 27-29 and 42-44 stand rejected under 35 USC §103(a) as being unpatentable over Cox as modified by Andersen as applied to claim 15, and further in view of US Patent No. 5489295 ("Piplani"). Applicant respectfully traverses the rejection. As discussed above, Cox and Andersen fail to teach or suggest the invention claimed in claim 15. For at least the same reasons discussed above, the above proposed combination also fails to show the claimed elements of claims 27-29 and 42-44, and, as a result, Applicant requests that the rejection be withdrawn.

Applicant grants the PTO permission to charge the deposit account no. 10-0750/BST/HRT0287 for any fees or charges related to this application. Applicant respectfully requests the Examiner to contact the below-signed if a discussion regarding the merits would advance prosecution of this case.

Respectfully submitted,

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Dated: December 17, 2007